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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,329 09/08/98 PORTMANN

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001095
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HM12/0620

EXAMINER

MORRIS, F

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

06/20/01

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Art Unit: 1625

DETAILED ACTION

Claims 1-25 are under consideration in this application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 12, 23 and 24 are rejected under 35 U.S.C. 101 and 35 USC 112 because the claimed invention is directed to non-statutory subject matter. Claims 11, 12, 23 and 24 violate 35 U.S.C. 101 and 35 U.S.C. 112, since they are drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District of Columbia 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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(f) he did not himself invent the subject matter sought to be patented.

Claims 1-25 are rejected under 35 U.S.C. 102(a), (b), (e) and/or (f) as being anticipated by Meier I (EP 199,262), II (US 4,789,680).

Meier I, II disclose the crystal form of the instant compound obtained by recrystallization from ethanol. Note example 35 of Meier I or example 4 of Meier II. Hence, the instant compound is deemed to be anticipated therefrom.

The factual situation here is well within the “Petering doctrine”: In re Petering et al., 49 CCPA 993, 301 F.2d 676, 133 USPQ 275 (1962). There the court affirmed a 102(b) rejection on the ground that the prior art, while it did not expressly name applicants’ claimed compounds, did describe such a limited class of only twenty compounds “that one skilled in this art would at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here” (133 USPQ at 280). Here we do not have anywhere near twenty possible compounds within the limited class described by the references.

Also, where a reference describes a sufficiently limited genus of a number of compounds closely related to another in structure, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Meier I, II in view of Munzel I (Progress in Drug Research, 10, 1966, pages 227-30), II (Progress in Drug Research, 14, 1970, pages 309-21) .

Meier I, II teach the crystal forms of the instant known compound. However, Meier I, II does not disclose the lines with interplanar spacings of the X-ray powder pattern of said form or other characterizing parameters thereof. Munzel I, II teach that compounds exist as polymorphs and retain pharmaceutical activity. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-a-vis* the known compound are suggested by the references. It would

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appear obvious to one skilled in the art in view of the references that the instant compound would exist in different polymorphic forms.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "modification" in claims 1-9, 11-14, 16-21, 23 and 24 is indefinite to its meaning since a modification refers not only to crystal forms but also to undefined possible modifications of the chemical structure.

The terms "preparations" and "preparation" in claims 10, 15, 22 and 25 does not clearly define a composition if that is what is contemplated by applicants. It is suggested that "preparation" be changed to --composition-- to clearly define it as such. Further, the claims fail to recite an effective amount of active ingredient.

The plural 's' on "preparations" makes claims 10, 15 and 25 read on mixtures rather than specific compounds.

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The expression "essentially pure form" in claims 9 and 21 is meaningless and fails to clearly define what is intended by applicants.

Regarding claims 7 and 16-20, the phrase "but has defects in the crystal lattice" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed thereby rendering the scope of the claim(s) unascertainable. It is assumed that the claimed compounds are no longer identical to "modification A". Further, claims 7 and 16-20 fail to specify what the defects are.

Claim 1 fails to clearly claim what is intended by applicants. How can "modification A" be identical to "modification A"? Claim 1 does not permit any defects in "modification A". Yet the dependent claims recite that modification A has defects.

The term "subindications" in claims 12 and 24 is unclear to its meaning.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 14 and 20 of U.S. Patent No. 4,789,680 in view of Munzel I,II.

As set forth supra, '489 disclose crystal forms of the instant known compound. Munzel I, II teach that the mere existence of further polymorphs of compounds is not in itself regarded as unexpected. Hence, patentable distinction is not seen.

Claims 1-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 17 and 21-24 of copending Application No. 09/129,330 in view of Munzel I, II. Ser. no. 09/129,330 teaches the crystal form B of the claimed compound. Munzel I, II teach that polymorphs are expected to exist. Hence, the instant crystal form is deemed to be an obvious optional variant of the crystal form B.

This is a provisional obviousness-type double patenting rejection.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

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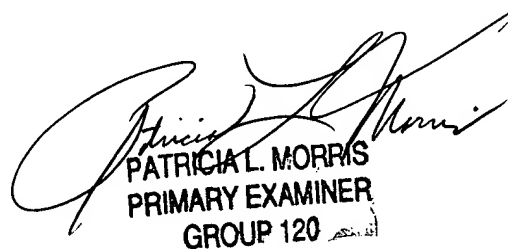
Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.


PATRICIA L. MORRIS
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plm

May 30, 2000



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
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Washington, D.C. 20231

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/125,329
Filing Date: September 8, 1998
Appellant(s): Portmann et al.

Paper No. 16

*mailed out
date, 6.20.01*

Thomas Hoxie
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed April 19, 2001.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

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A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The amendment after final rejection filed on January 19, 2001 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-9, 13, 14, 16-21, 30 and 31 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

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199,262	Meier I	10-1986
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4,789,680	Meier II	12-1988
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Munzel I, Progress in Drug Research, vol. 10, pgs. 227-30 (1966).

Munzel II, Progress in Drug Research, vol. 14, pgs. 309-321 (1970).

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Upon reconsideration, the rejection of claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 under 35 U.S.C. 102 and 35 U.S.C. 112 have been withdrawn.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 stand rejected under 35 U.S. 103(a) as being unpatentable over the combined teachings of Meier I, II in view of Munzel I, II.

Meier I, II teach the crystal forms of the instant known compound. Note example 35 of Meier I or example 4 of Meier II. However, Meier I, II does not disclose the lines with interplanar spacings of the X-ray powder pattern of said form or other characterizing parameters thereof, whereas the instant claims disclose specific X-ray diffraction pattern for the claimed compounds. Munzel I, II teach that compounds exist as polymorphs and retain pharmaceutical activity. Hence the claimed crystalline form as well as its relative selectivity of properties, *vis-a-vis* the known compound are suggested by the references. It would appear obvious to one skilled in the art in view of the references that the instant compound would exist in different polymorphic forms.

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Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 14 and 20 of U.S. Patent No. 4,789,680 in view of Munzel I, II.

Meier II '489 discloses the crystal forms of the instant known compound. Munzel I, II teach that the mere existence of further polymorphs of compounds is not itself regarded as unexpected. Hence, patentable distinction is not seen.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 17 and 21-23 of copending Application No. 09/599,688 in view of Munzel I, II.

Ser no. 09/599,688 teaches the crystal form B of the claimed compound. Munzel I, II teach that polymorphs are expected to exist. Hence, the instant crystal form is deemed to be an obvious optional variant of the crystal form B.

This is a provisional obviousness-type double patenting rejection.

(11) Response to Argument

Appellants assert that the Meier references do not suggest or teach the crystalline forms discovered by appellants or a method of making the crystalline forms. It is well known in the art that compounds exist in different crystalline forms. One of ordinary skill in the art would have been motivated to make these crystalline forms with the expectation that they would have better solubility, stability and/or purity. The process by which the different crystalline forms are likewise known in the art. No unexpected or unobvious properties are noted.

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In the predecessor Court, the standard for different physical forms, purity, or other physical characteristics, was set forth in *In re Cofer*, 354 F.2d 664, 148 U.S.P.Q. 268 (CCPA 1966) wherein the differences are rendered obvious by the prior art are not patentable. The beginning of the second series of the U.S.P.Q. since 1983 to the present time, the Court of Appeals for the Federal Circuit has only dealt with one published case dealing with polymorphs and that decision is "*Glaxo Inc. V. Novapharm Ltd.*, 34 U.S.P.Q. 2d, 1565 (Fed. Cir. April 1995)". This decision was drawn to an infringement suit, covered such topics as, Infringement Defenses, Fraud Unclean hands, Patentability, Validity, Best mode, Inequitable Conduct and the like. The issue of obviousness under 35 U.S.C. 103 was not an issue. Yet, the dicta of the Court seemed to indicate that changing the physical forms was not pre se patentable and that objective evidence must be shown in the form of a declaration by applicants clearly showing an unexpected superior result on a side-by-side comparison. Appellants have failed to provide any showing establishing unexpectedly superior results of the claimed crystal form *vis-a-vis* the known compound of Meier I, II. It is known in the prior art that changing solvents with routine experimentation results in different physical forms. Appellants much know that changing physical forms according to legal precedent does not enable applicants "Carte Blanch" when dealing with this type of technology. Otherwise an applicant(s) could extend a monopoly for ever, which is not the intent of the patent.

Appellants in response to the final rejection for the first time submitted two exhibits. Appellants failed to show why they had not been earlier presented. Assuming *arguendo* that

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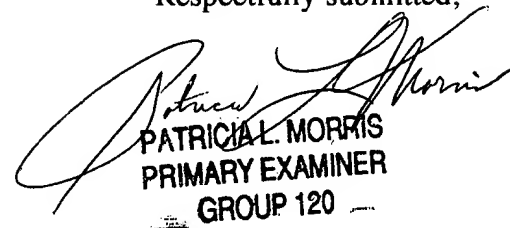
they are indeed proper exhibits, document 1 (CGP 33101) is in German and not in english. The exhibit has not been considered. Document 2 fails to establish any superior unexpected results for the instant crystals *vis-a-vis* the known compound. The instant crystals and the prior art compound are both useful for the treatment of epilepsy. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-a-vis* the known compound are suggested by the references. It is expected that the instant crystals and prior art compound would be useful for the treatment of epilepsy.

Contra to appellants' arguments regarding the double patenting rejections, appellants have failed to establish any patentable distinction between the crystalline forms, the crystal form B of 09/599,688 or the prior art compound of '489. The absence of evidence concerning the relative properties of the claimed and art compounds does not result in a conclusion that the prima facie obviousness of the claimed compounds has been rebutted. It simply leaves the prima facie obviousness unrebutted. The record herein clearly is not sufficient to permit a conclusion that the claimed crystals are unexpectedly more effective than the reference compounds even for the limited purpose of treating epilepsy.

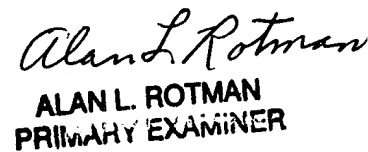
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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

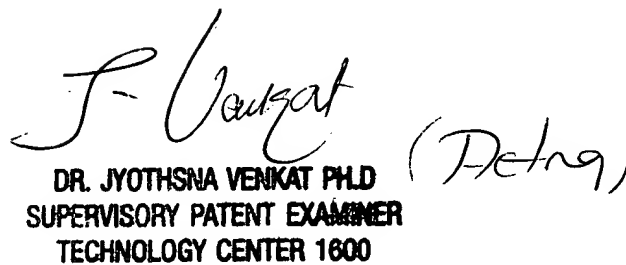

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